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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,780	07/05/2001	Gary W. Wood	70012590-04	5013

27910 7590 07/28/2003

STINSON MORRISON HECKER LLP  
ATTN: PATENT GROUP  
1201 WALNUT STREET, SUITE 2800  
KANSAS CITY, MO 64106-2150

EXAMINER
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HARRIS, ALANA M

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 07/28/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/899,780	WOOD, GARY W.
	Examiner Alana M. Harris, Ph.D.	Art Unit 1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 14 May 2003.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 13-17 and 23-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 13-17 and 23-28 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |  |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                               | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)           | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other:   |

**DETAILED ACTION**

***Response to Arguments***

1. Claims 13-17 and 23-28 are pending.  
Claims 19-22 have been cancelled.  
Claims 23-28 have been added.  
Claims 13-17 and 23-28 are examined on the merits.
  
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Priority***

3. Applicant has amended the specification to include the current status of the application in the first line of the specification.

***Oath/Declaration***

4. Applicant submitted a supplemental declaration, received April 15, 2003 in lieu of the defective declaration originally presented. The supplemental declaration contains all the required information. Applicant claims domestic priority under Title 35, United States Code §120.

***Drawings***

5. The formal drawings submitted April 15, 2003 within Paper number 11 have been approved by the draftsman.

***Sp cification***

6. The application has been amended to properly reflect trademarks.

***Withdrawn Rejections***

***Claim Rejections - 35 USC § 112***

7. The rejection of claims 19-22 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been withdrawn in light of the cancellation of the claims.

***Claim Rejections - 35 USC § 102***

8. The rejection of claims 13-17 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent number 5,766,920 (issued June 16, 1998/ IDS reference) is withdrawn in light of Applicant's arguments. Claims 19-22 have been cancelled.

***New Grounds of Rejection***

***Claim Rejections - 35 USC § 103***

9. Claims 13-17, 23, 24 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent number 5,766,920 (issued June 16, 1998/ IDS reference), further in view of U.S. Patent number 5,290,551 (issued March 1, 1994/ IDS Reference).

U.S. Patent # 5,766,920 teaches a process of producing and enhancing a population of immunoreactive cells, polyclonal T cells, see column 2, line 11-column 3,

line 16. "The process involves removing a patient's mononuclear cells and exposing the cells in vitro to substances which enhance the immune function of the cells", see column 2, lines 15-18. The mononuclear cells may also be derived from tumor or tumor-draining lymph node, see column 2, lines 42-44. The mononuclear cells, such as peripheral blood mononuclear cells (PBMC) are contacted with OKT3 (art known and the same as anti-CD3) to yield a population of immunoreactive cells, see column 2, lines 23-36, column 3, lines 44-49. The immunoreactive cells are further exposed to an immune stimulant such as an antigen, an inflammatory molecule or a cytokine, such as granulocyte macrophage-colony stimulating factor (GM-CSF) and interleukin-2 (IL-2) in vitro to yield a population of immunoreactive cells, see column 3, lines 6-12 and column 5, lines 2-16; 47-63. The PBMC were obtained from patients by leukopheresis, see column 9, lines 25-27. This method of enhancing and expanding the T cell effector population is effective in the treatment of any type of cancer, including both solid tumors and hematologic tumors, such as breast carcinoma and astrocytomas, see column 7, lines 30-36. Patent '920 does not teach a method of vaccinating a patient with a vaccine comprised of the patient's own malignancy and an immunologic-adjuvant and that the removal of primed peripheral blood T lymphocytes from the patient.

However, U.S. Patent #5,290,551 teaches the intradermal injection of a vaccine consisting of autologous, cyropreserved, irradiated tumor cells mixed with the immunological adjuvant Bacille Calmette-Guerin (BCG), see column 4, lines 60-63. The patients peripheral blood T lymphocytes are primed at this stage. It would be *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was

made to implement the teachings of both patents to vaccinate a cancer patient with their own malignancy and immunologic adjuvant in order to augment the patient's immune response in order to treat cancer and establish a primed population of effector T lymphocytes capable of recognizing the malignancy. With this augmentation of the patient's immune system intrinsically primed peripheral blood T lymphocytes would be a part of the mononuclear population to be removed. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by the teachings of these references that the endpoint is the effective treatment of cancer. Moreover, the generation of therapeutically relevant numbers T-lymphocytes specifically sensitized with increased specificity for the malignancy would be brought about utilizing the teachings of both patents. And patent '920 sets forth an analogous method in which "[m]ononuclear cells taken from a patient afflicted with a complex chronic viral disease may ...be processed...to yield immunoreactive cells which can then be returned to the patient to augment the patient's immune response to the pathogen", see column 7, lines 40-44.

10. Claims 13-17 and 23-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent number 5,766,920 (issued June 16, 1998/ IDS reference), further in view of U.S. Patent number 5,290,551 (issued March 1, 1994/ IDS Reference).

The teachings of the patent have been established in the preceding paragraphs. Neither patent teaches that the patient is vaccinated at multiple body sites with at least  $5 \times 10^6$  malignant cells and the patient is vaccinated at the time of initial diagnosis.

However, although the claims recite these specific treatment points in reference to time of diagnosis and dosages of malignant cells, no positive recitation of the methods distinguishes the claims over the references. Therefore, the references read on the treatment at the time of initial diagnosis and at multiple body sites with the specified amount of malignant cells. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to begin cancer treatment in an expeditious manner in order to impede metastasis, as well as administrating in various sites to effectively eradicate the tumor cells that may have metastasized and to further limit comprising the individual's health. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success since dosages of any composition for treatment must be adjusted and optimized and primed/activated cells reinfused into patients enhances the immune system to treat cancer immediately. Thus the claimed subject matter is considered obvious over the prior art, absent sufficient factual evidence to the contrary.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (703) 306-5880. The examiner can normally be reached on 6:30 am to 4:00 pm, with alternate Fridays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4315 for regular communications and (703) 308-4315 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

**ALANA HARRIS  
PATENT EXAMINER**

*Alana M. Harris*

Alana M. Harris, Ph.D.

July 24, 2003